

(12) UK Patent Application (19) GB (11) 2 359 256 (13) A

(43) Date of A Publication 22.08.2001

(21) Application No 0100554.5

(22) Date of Filing 09.01.2001

(30) Priority Data

(31) 09489336	(32) 21.01.2000	(33) US
(31) 00012753	(32) 05.10.2000	(33) FR

(71) Applicant(s)

Sofradim Production
(Incorporated in France)
116 Avenue du Formans, 01600 TREVOUX, France

(72) Inventor(s)

Victor Scetbon

(74) Agent and/or Address for Service

Urquhart-Dykes & Lord
8th Floor, Tower House, Merrion Way, LEEDS,
LS2 8PA, United Kingdom

(51) INT CL⁷**A61F 2/00**

(52) UK CL (Edition S)

A5R RAP RAT R131

(56) Documents Cited

WO 98/35632 A **WO 00/74633 A** **US 6010447 A**
US 5899909 A

(58) Field of Search

INT CL⁷ A61B 17/04 , A61F 2/00
ONLINE: EPODOC, WPI, JAPIO

(54) Abstract Title

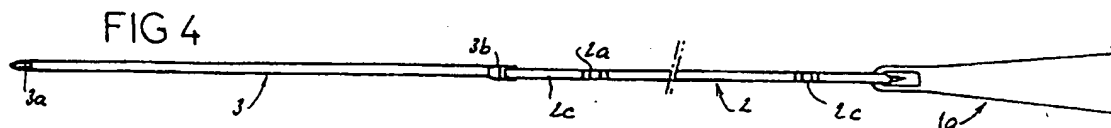
Percutaneous device for treating urinary stress incontinence in women using a sub-urethral tape

(57) This device for treating urinary stress incontinence in women comprises:

- a flexible and elongate urethra-support means (1a) comprising a tape for supporting the urethra and a protective sheath lying flat and enveloping said tape;
- a puncturing needle (3) with an active distal end (3a) and a proximal end connected to a first end of the flexible means.

According to the invention, the proximal end (3b) of the puncturing needle is connected to the first end of the flexible means by virtue of an intermediate traction element (2), the second end of the flexible means being free or extended by an additional intermediate traction element.

The traction element (2) may be a traction lace (Fig.4) attached via loops (2c) or a semirigid tubular element (20) which may be screwed to flexible means (1a) and needle (3) (Figs 7-11; not shown). The sheath may be split into two parts (51,52) by sliding them in opposite directions relative to the tape and includes splitable means (15) at the centre of the sheath (5) (Figs 1, 2 and 7, not shown). A surgical technique to implant the device is also described (Figs 12-21).



Best Available Copy

GB 2 359 256 A

FIG 1

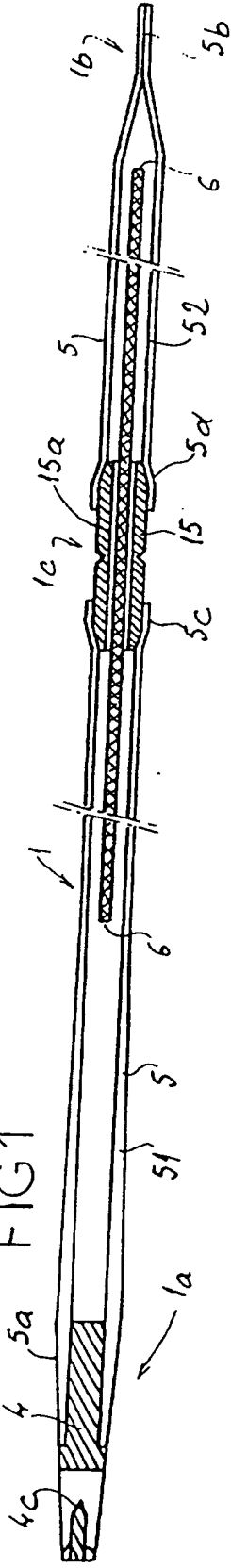


FIG 2

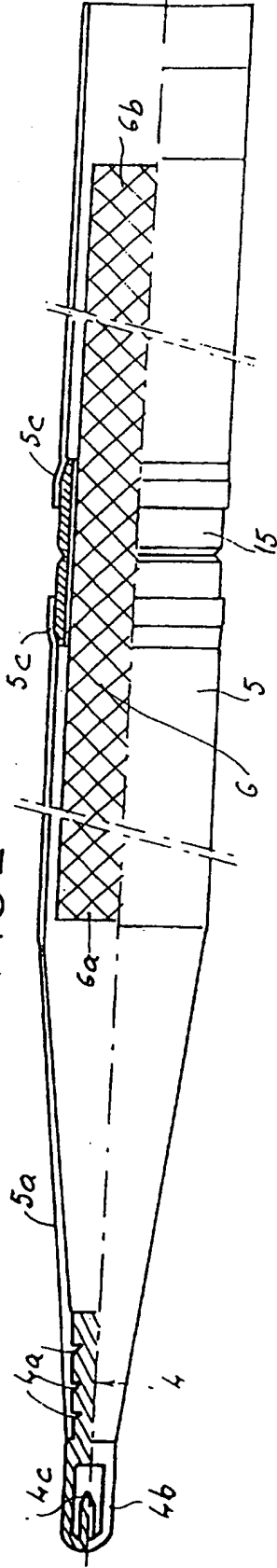


FIG 4

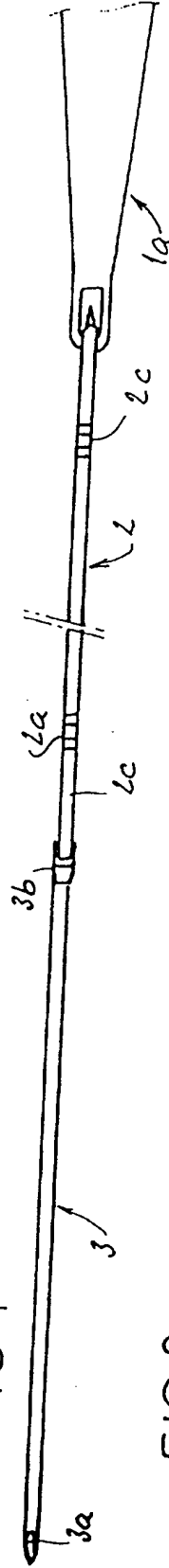


FIG 3

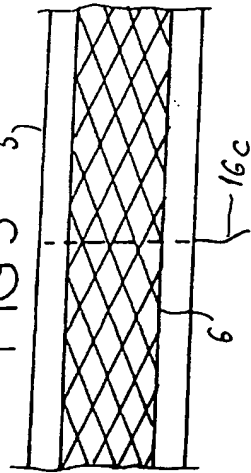


FIG 5

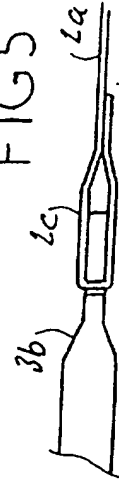
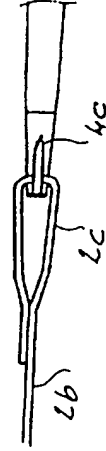


FIG 6



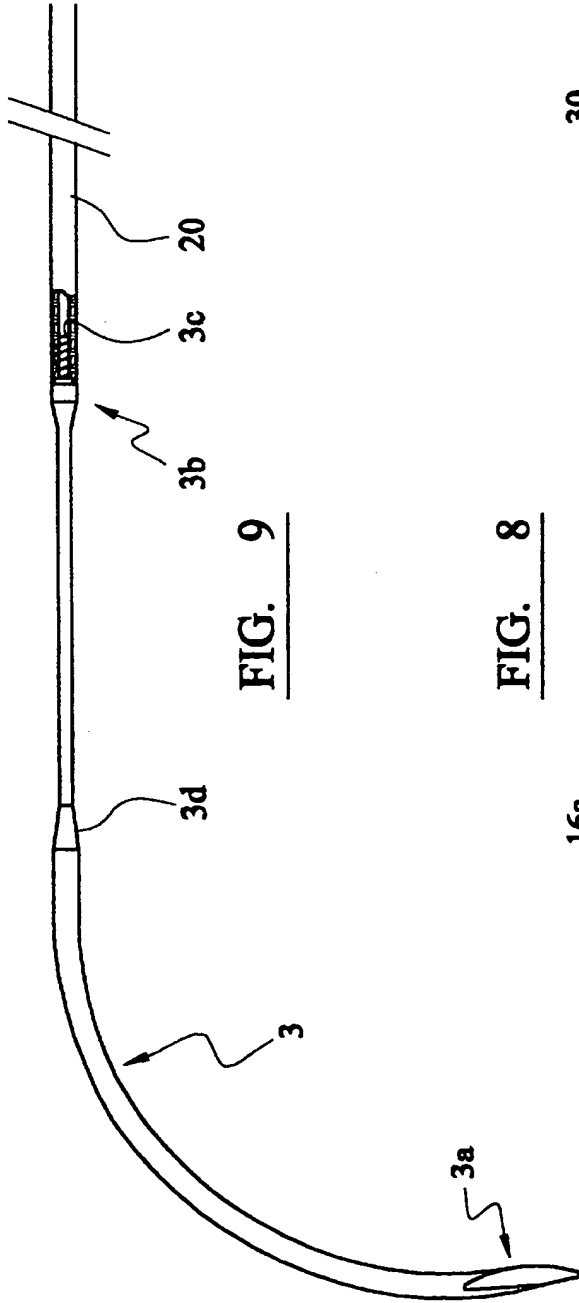
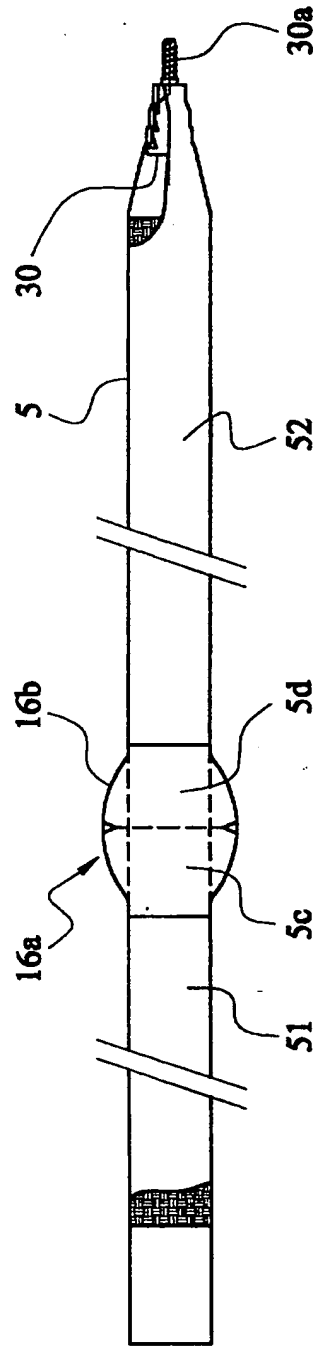
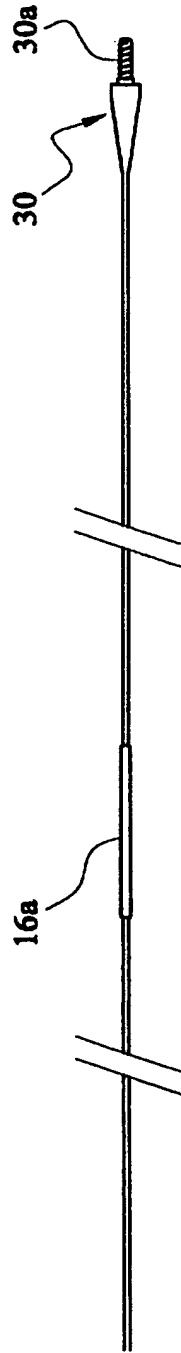
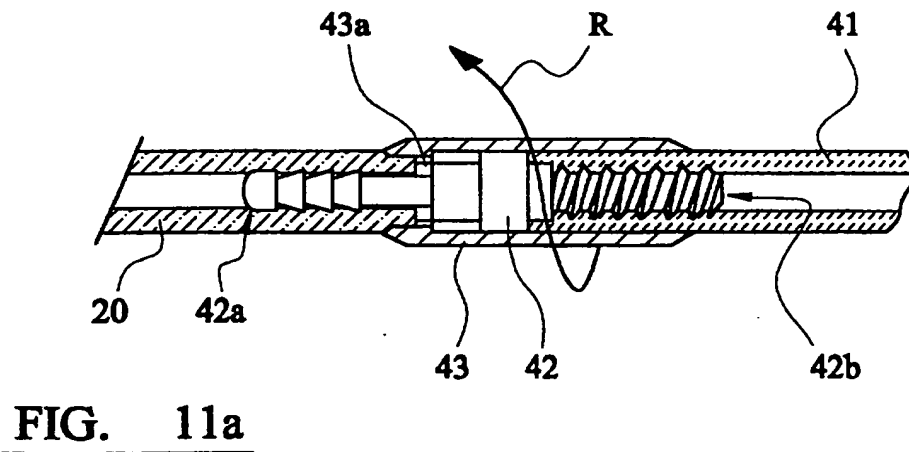
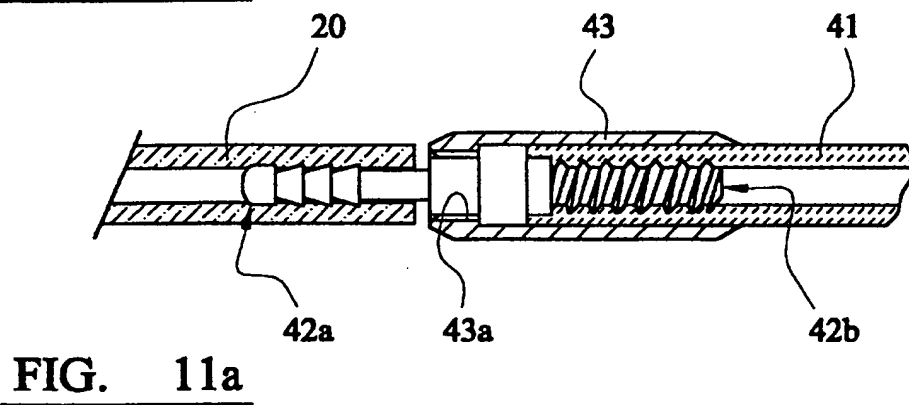
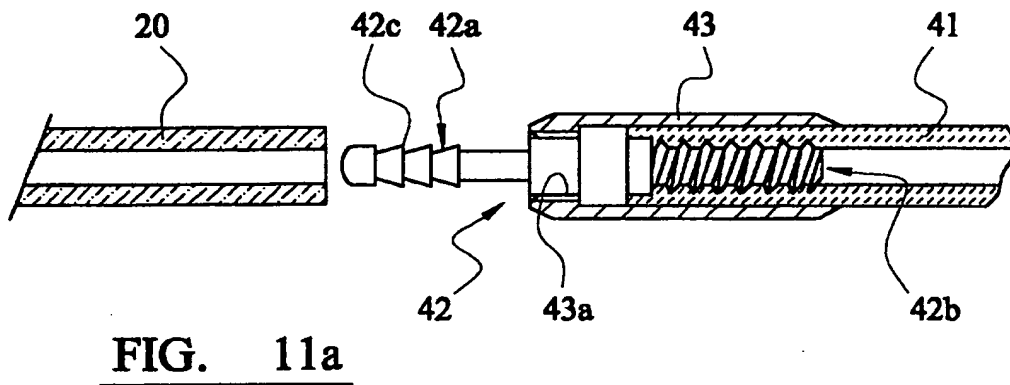
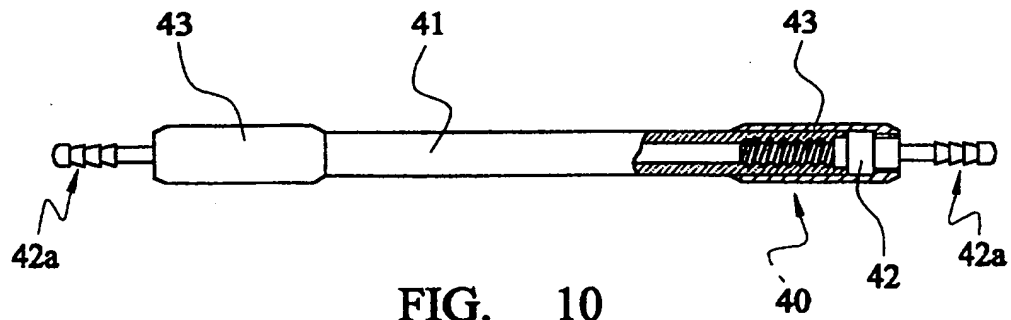


FIG. 8





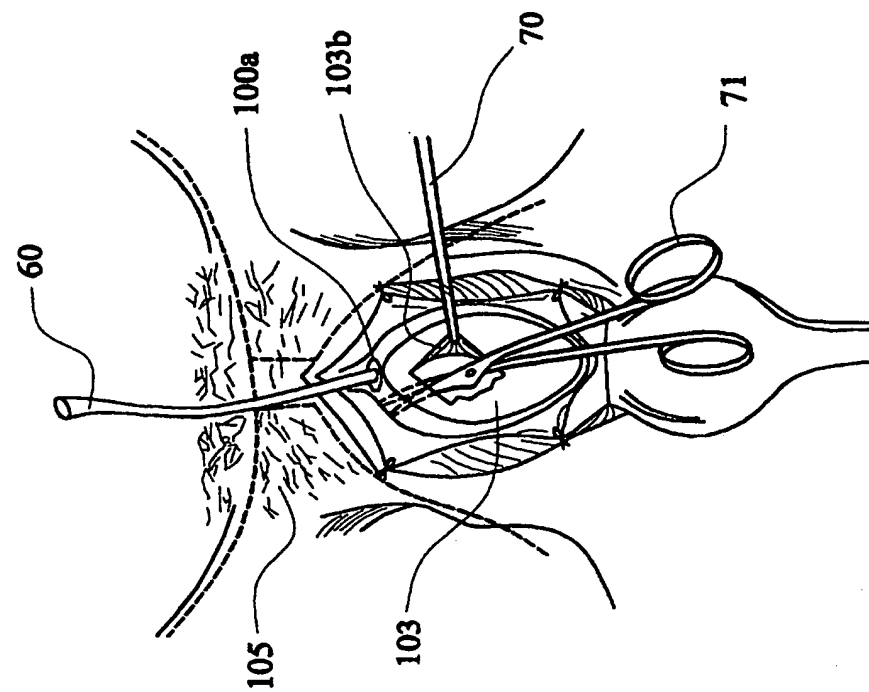


FIG. 12

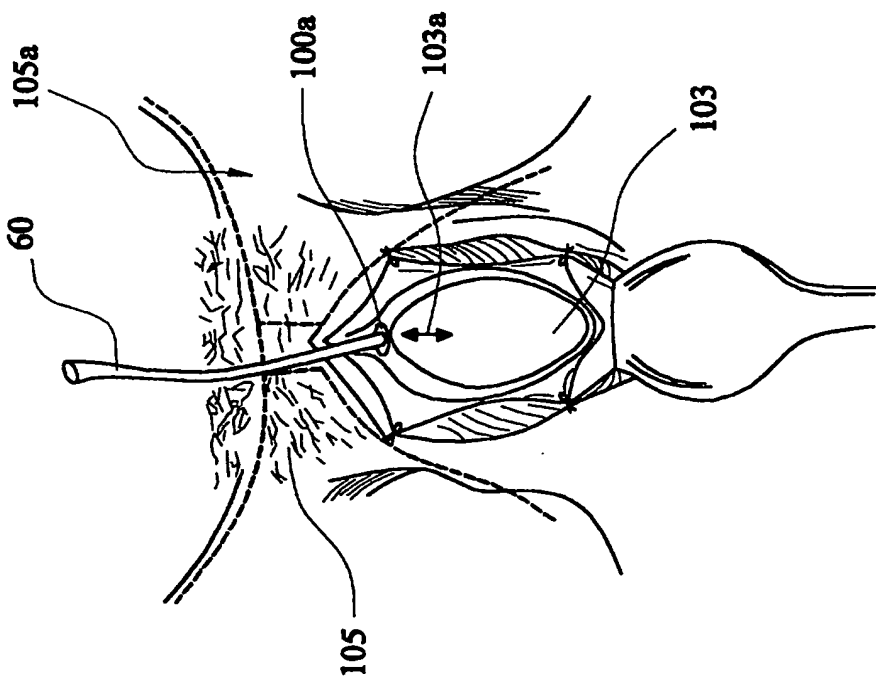
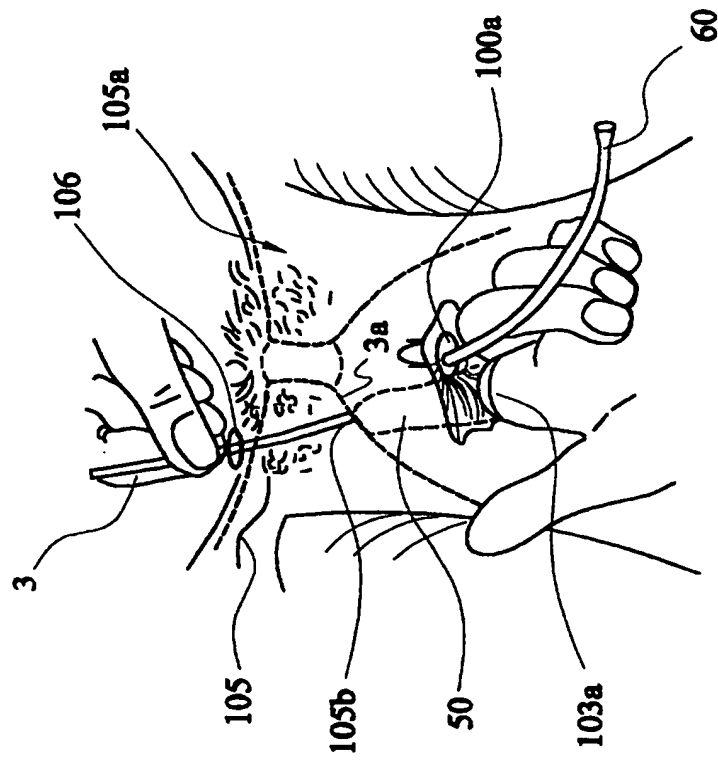
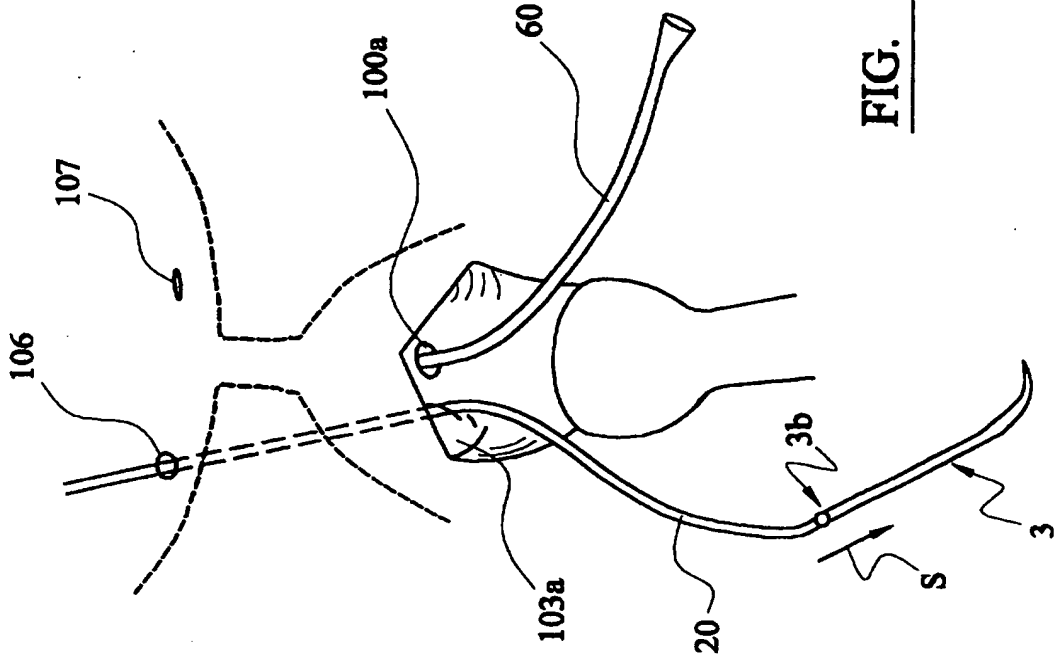


FIG. 13



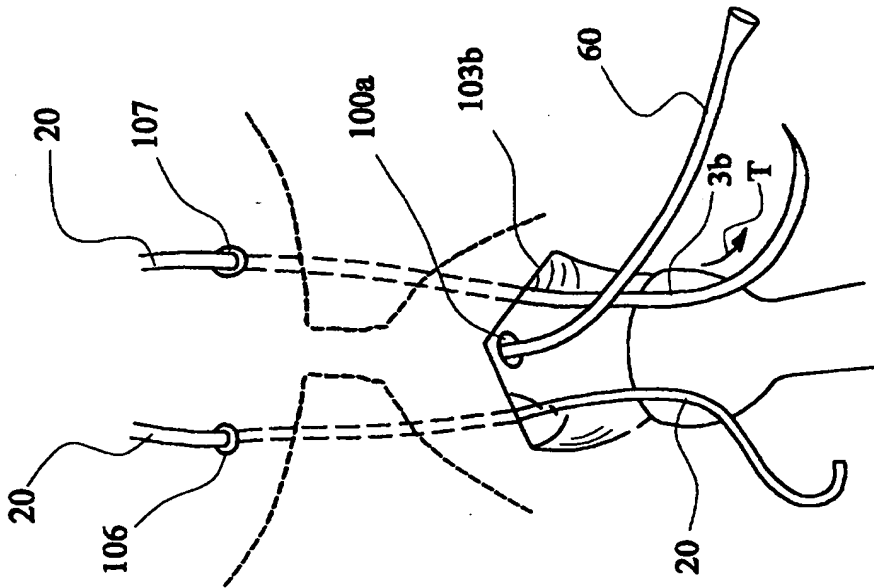


FIG. 16

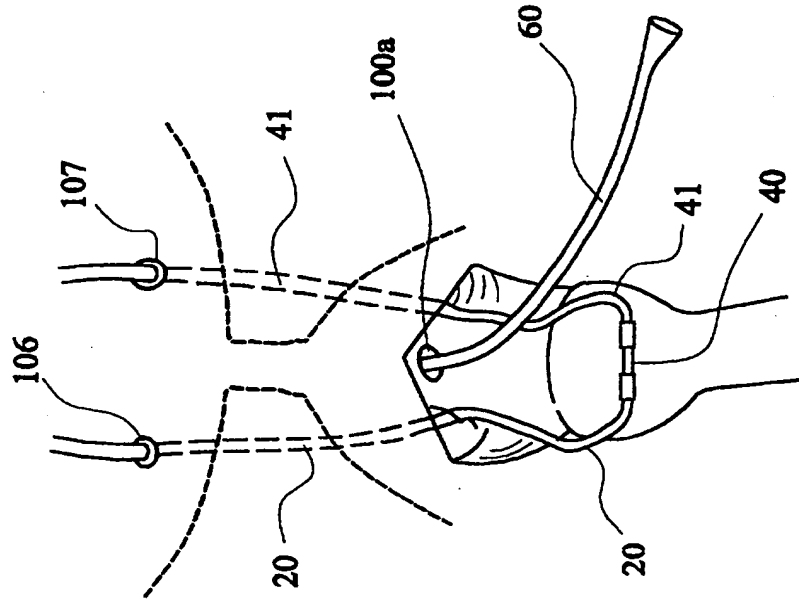


FIG. 17

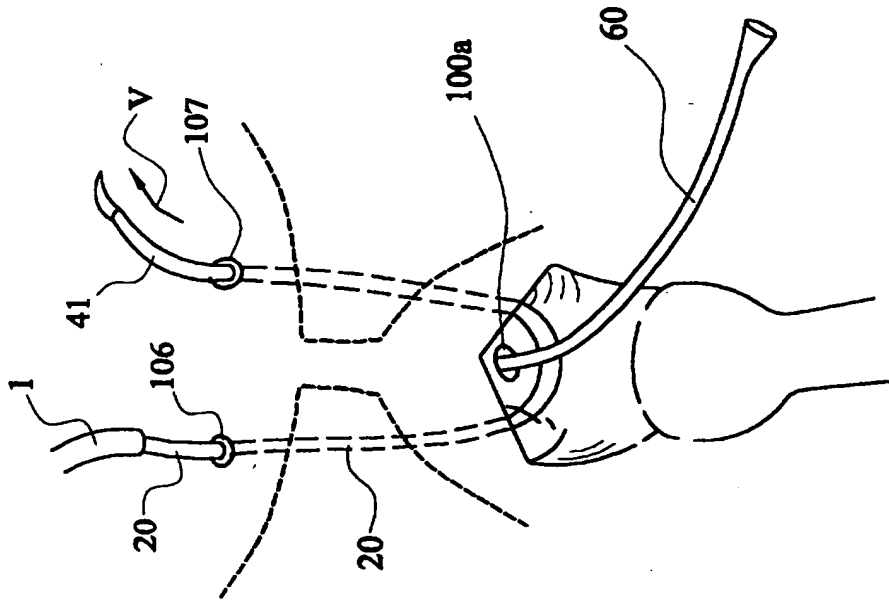


FIG. 18

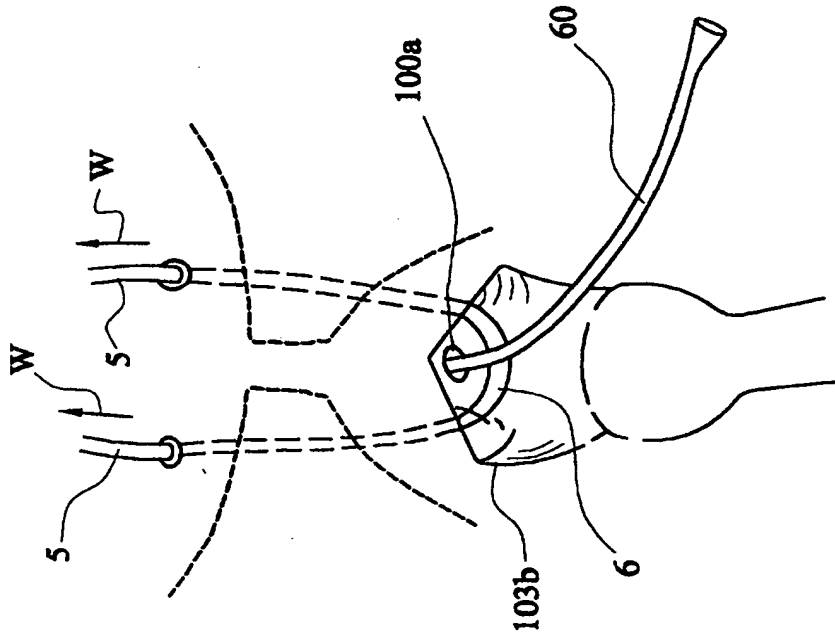
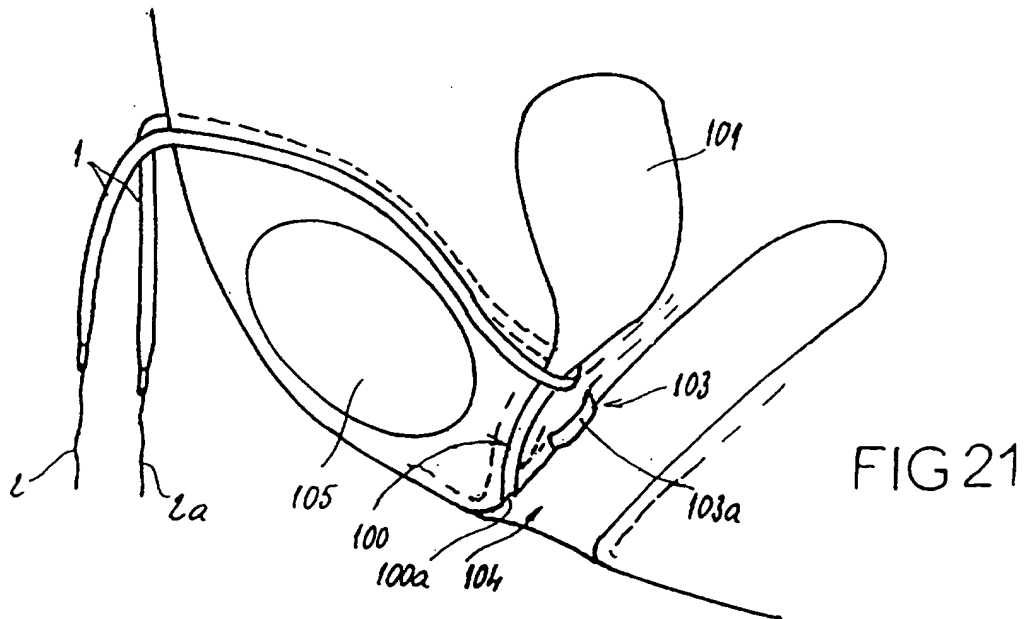
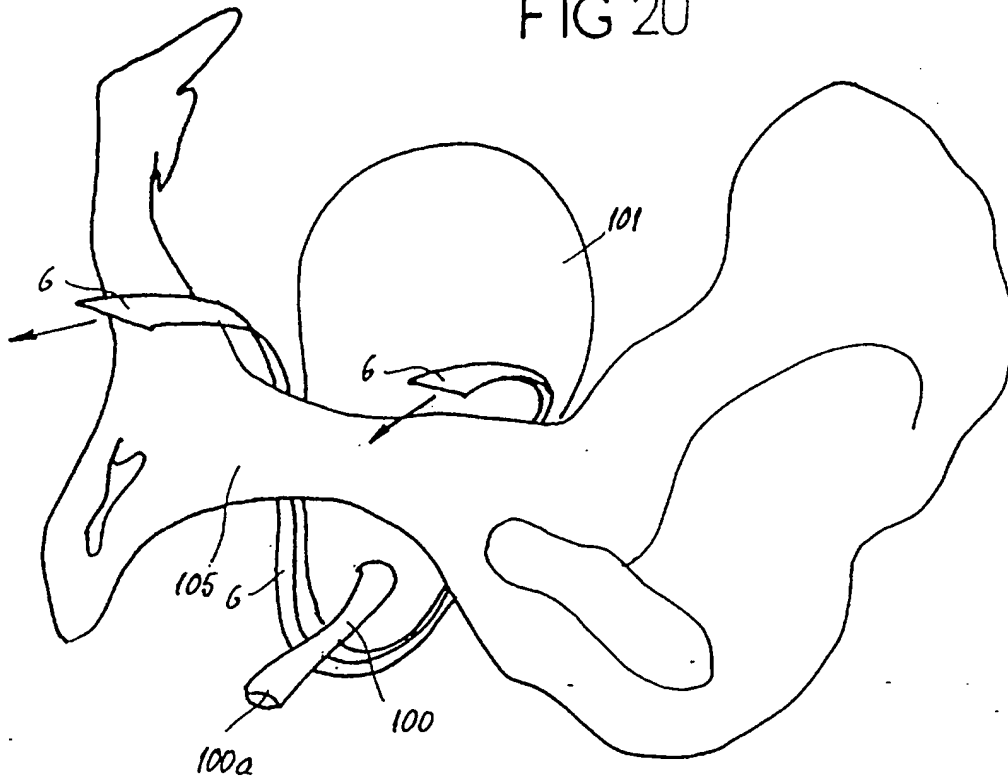


FIG. 19

FIG 20



Background of the invention

The present invention relates to the problems of urinary incontinence in women and more specifically to the problems of urinary stress incontinence. The invention relates more particularly to a percutaneous device for treating urinary stress incontinence in women using a sub-urethral tape.

10 Description of the prior art

These problems are currently treated during surgical interventions under local, regional or general anesthetic and consist in implanting a tape in such a way as to support the urethra without tension.

Thanks to the regional or local anesthesia, the surgeon can immediately check that continence has been restored, with the participation of the patient.

An intervention such as this is performed using an appropriate device including specialist instruments.

In particular, it is known practice in treating urinary incontinence to use a tape that can be implanted under the urethral canal, and a sheath surrounding the tape, said sheath being withdrawn from said tape after the latter has been implanted.

There is a known device for treating urinary stress incontinence in women, comprising:

- a flexible and elongate urethra support means comprising a tape and a protective sheath lying flat and enveloping said tape,

- and a puncturing needle with an active distal end and a proximal end connected to a first end of the flexible means.

Thus, document US-A-5 899 909 discloses a treatment method and a treatment device for incontinence. The device described, which allows a tape to be placed under the urethra, comprises two special needles. These are mounted in turn, by screw fastening, on a reusable steel insertion tool made of a handle and

of a threaded manipulator rod which allows each of said needles to be manipulated in turn. Each needle is fixed to one of the ends of the tape-sheath assembly.

Each end of the tape-sheath assembly is fixed
5 to a frustoconical part of one end of the corresponding needle, using a shrunk or bonded polymer ring.

The tape is therefore implanted by introducing each of the needles through a short incision in the anterior vaginal wall, these incisions being one on
10 each side of the central position of the urethra.

The needles implanted in turn using the manipulator rod, then travel up around the bladder and the pubic bone and reemerge from the body through incisions made in the abdominal wall in the suprapubic
15 region.

The two halves of the sheath which overlap at the middle of the tape are withdrawn by pulling on the ends that emerge from the suprapubic incisions.

A device such as this requires the use of
20 ancillaries of the insertion handle and rigid intravesical catheter guide type especially designed for this type of surgical intervention.

The known surgical intervention also has a disadvantage insofar as the needles are introduced into
25 the anterior wall of the vagina to reemerge in the suprapubic region. This bottom-upward path cannot be controlled precisely for going around the base of the bladder. Vesical perforations are far from uncommon. They need to be recognized peroperatively through the
30 use of two cystoscopies and entail repeating the maneuvers under more difficult conditions.

The two accessories (manipulator handle and rigid probe guide) must therefore be available to the surgical team during each intervention, having been
35 previously washed, packaged and sterilized prior to each use. In addition, this lateral passage with respect to the bladder, with a vaginal point of entry runs the risk that the point of the needle will injure the iliac vessels in the retrocrural region. These

vascular lesions have already been observed and have led to fatalities.

Another drawback of the known device lies in the difficulty of repeating the intervention, using the same device, when cystoscopy reveals that the sheath-tape assembly has taken the wrong course. Retreat may prove difficult and tricky for the sheath, and especially for the bulky needles.

The sheath-tape assembly has therefore to be cut and the device can no longer be used to take a different path; it also carries the risk of no longer being sterile as it may have been contaminated during these additional maneuvers.

15 Summary of the invention

The object of the present invention is to overcome the drawbacks of the prior art so as to obtain a different operative technique which is easier, quicker and safer (as far as the bladder and vessels are concerned). The device proposed makes it possible to employ this different technique which will be described in detail later on in this description.

Another object of the present invention is to produce a device for treating urinary incontinence which can be reused easily if it is introduced into the body in a non-optimum path, an eventuality which, according to the present invention, can occur only under exceptional circumstances if there is very strong adhesion between the bladder and the pubis as the result of earlier interventions.

According to the invention, the proximal end of the puncturing needle is connected to the first end of the flexible means by virtue of an intermediate traction element, the second end of the flexible means being free or extended by an additional intermediate traction element.

According to one embodiment of the device according to the invention, the protective sheath

completely envelopes the tape, including its first and second ends.

According to one embodiment of the invention, the sheath can be split into two parts that can be
5 separated by sliding them in two opposite directions relative to the tape, said device comprising a splittable means between the two central and adjacent ends of the sheath.

According to another embodiment of the device
10 according to the invention, it comprises a filament arranged roughly at right angles to the longitudinal axis of the sheath, so as to cut said sheath when traction is exerted on said filament.

According to one embodiment of the device
15 according to the invention, the sheath is made of a fluoropolymer-based heat-shrinkable material.

According to one embodiment of the device according to the invention, the tape is formed from a macroporous knitted material.

According to one embodiment of the invention, the tape in its central region has a resorbable hydrophilic film reducing the risk of adhesion to or
20 the risk of erosion of the urethra.

According to one embodiment of the device
25 according to the invention, the puncturing needle has a curved part continuously adjacent to a roughly straight part ending in its proximal end.

According to one embodiment of the invention, the intermediate traction element is a traction lace.

According to one embodiment, the device
30 according to the invention comprises an end piece onto which the sheath is heat shrunk and to which the traction lace attaches.

According to one embodiment according to the
35 invention, the traction lace has a length roughly equal to the length of the flexible means.

According to a preferred embodiment of the device according to the invention, the intermediate traction element is tubular.

According to one embodiment of the device according to the invention, the intermediate traction element and the puncturing needle are assembled by screwing.

5 According to one embodiment of the device according to the invention, the traction element consists of two parts of roughly the same length, placed end to end and joined together removably, for example by screwing using a coupling.

10 According to one embodiment of the device according to the invention, the puncturing needle is the only puncturing needle.

Brief description of the drawings

15

Other features and advantages will also become apparent from the detailed nonlimiting description given hereinafter with reference to the appended drawing, in which:

20 - figure 1 depicts a view in section of the flexible means of the device according to the invention,

25 - figure 2 depicts a view from above, with partial cutaway, of the flexible means shown in figure 1.

 - figure 3 depicts, in part, another exemplary embodiment of the flexible means of figure 2,

 - figure 4 depicts a partial view of a device according to the invention,

30 - figures 5 and 6 depict details of figure 4,

 - figures 7 and 8 depict another embodiment of the flexible means of the device according to the invention,

35 - figure 9 depicts a partial view of another embodiment of the device according to the invention,

 - figures 10, 11a, 11b and 11c depict details of the device depicted in figure 9,

- figures 12 to 19 diagrammatically depict the surgical method employed using the device according to the invention,

5 - figures 20 and 21 diagrammatically depict the position of the device according to the invention in the body of a patient.

Description of the preferred embodiment(s)

10 The device partially depicted in figures 1, 2, 3 and 4 comprises an elongate flexible means 1 generally consisting of a composite band.

 The flexible means 1 is shown only in part and not in its entire length. It generally has a flattened
15 and elongate shape.

 The first end 1a of the flexible means 1 can be connected to an intermediate traction element 2 (cf. figure 4) and the second end 1b is free or extended by an additional intermediate traction element (not
20 depicted).

 The device according to the invention also comprises a puncturing needle 3, for example made of stainless steel, connected to the intermediate traction element.

25 The flexible means 1 comprises a protective sheath 5 lying flat and enveloping a tape 6.

 The single puncturing needle 3 has an active distal end 3a and a proximal end 3b connected to the first end 1a of the flexible means 1.

30 The proximal end 3b of the puncturing needle 3 is connected to the first end 1a by virtue of an intermediate traction element 2. The proximal end 3b is thus a non-puncturing end.

 The distal end 3a is at the end of a curved
35 part continuously adjacent to a roughly straight part ending in the proximal end 3b.

 The puncturing needle has, for example, a diameter of 3.5 mm in its curved part.

The proximal end 3b is also equipped with an attachment means allowing it to make a connection with the intermediate traction element.

5 The protective sheath 5 completely envelopes the tape 6, including its first end 6a and its second end 6b.

10 The sheath 5 is made, for example, of a fluoropolymer-based heat-shrinkable material. The material of which the sheath 5 is made is chosen so that it is perfectly impervious to completely isolate the tape 6 intended to be implanted in the body of the patient from contact with the skin and mucosa when following the implantation paths through said body.

15 The sheath 5 may also exhibit properties of low coefficient of friction. These properties are therefore found both on the inside and on the outside of the sheath 5, so as, on the one hand, to ensure good separation from the tape 6 and, on the other hand, to reduce the friction inside the body of the patient when
20 the flexible means 1 is being pulled.

The tape 6 advantageously has a width of between 6 and 14 mm, preferably between 10 and 12 mm and a length of between 30 and 50 cm, preferably around 40 cm.

25 The tape 6 is preferably formed from a macroporous knitted material.

The latter consists for example of an open knit made of single stranded polypropylene of between 0.12 and 0.16 millimeter thick and made up of two layers
30 formed by two threaded guide bars each - one full guide and one empty guide - these two guides being moved symmetrically for open mesh according to the following chart:

35 - bar I: 01-12-32
- bar II: 32-21-01.

The tape 6 is cut to length in the warp direction of the knit.

The latter, for example 12 mm wide, therefore has the following properties:

- a breaking strength in the warp direction of $105N \pm 20\%$,
- an elongation at break in the warp direction of $92\% \pm 20\%$
- 5 - an elongation of 36% under a force of 20N
- an onset of curling with a force of 6N and an elongation of 15%.

The expression "curling" is intended to mean the property whereby the tape 6 rolls up on itself spontaneously about its longitudinal axis under longitudinal tensile stress.

The tape 6 has attractive advantages and, in particular, low emission of particles as it is stretched, and curling which occurs only under high stress (6N). None of these aforementioned properties in any way detracts from the porosity of the tape 6.

The sheath 5 can preferably be split into two parts 51, 52 which can be separated by sliding them in two opposite directions with respect to the tape 6.

20 For this purpose, the device according to the invention has a splittable means 15, roughly at the middle of the sheath 5 and the two ends of which are secured to the corresponding and adjacent central ends 5c, 5d of said sheath 5.

25 The material of the splittable means 15 is chosen from materials of the thermoplastic type approved for surgical application.

30 The connection between, on the one hand, the central ends 5c, 5d of the two parts 51 and 52 respectively and, on the other hand, the splittable center 15, is obtained by any means able to make said sheath 5 impervious. The same is true of the free end 5b of the sheath 5, which is quite simply plugged or sealed.

35 The splittable means 15 comprises a flat slit 15a passing through it from one longitudinal end to the other, for the free passage of the tape 6.

The splittable means 15 may be replaced in an embodiment depicted in figures 7 and 8, by an adhesive

sleeve 16a joining the ends of the two splittable parts 51 and 52 of the sheath 5. This sleeve is weakened, for example by a partial broken cut or a line of weakness in the sheath 5. The adhesive sleeve 16a made of a flexible material which sticks firmly to the central ends 5c, 5d, also has a precut tab 16b to make said sleeve 16a easier to tear and therefore make the sheath 5 easier to split into the two parts 51 and 52.

According to another method of embodiment of the device according to the invention, the one-piece sheath 5 incorporates a filament 16c arranged roughly at right angles to the longitudinal axis of the sheath 5, so as to cut said sheath 5 when traction is exerted on said filament 16c. An example such as this is depicted, for example, in figure 3. The filament 16c is advantageously in color so that it can easily be identified.

The sheath 5 can thus be split in the central zone 1c of the flexible means 1 so as to release the tape 6 inside the body of the patient.

The intermediate traction element is, according to one method of embodiment of the invention, made, for example, with a traction lace 2 depicted in Figure 4.

The device according to the invention also comprises an end piece 4 to which the sheath 5 is attached by heat-shrinking. The sheath 5, more particularly its first end 5a, is thus heat shrunk in a sealed manner onto the end piece 4.

As depicted in figure 2, the end piece 4 comprises anchoring notches 4a into which the heat-shrunk material of which the sheath 5 is made engages. The end piece 4 is made, for example, of a piece of stainless steel or any other rigid material capable of coming into contact with intracorporal tissue.

Advantageously, the flexible means 1 comprises a knotting eye 4b (cf. figure 4) arranged on the outside of the sheath 5. This eye 4b consists, for example, of a closed loop and may, as appropriate, have a point 4c intended to pass through and catch on one

end of the traction lace 2 or any other intermediate traction element.

5 The knotting eye 4b is for example made integrally in the end piece 4. The latter may also have a roughly flattened and partially frustoconical shape so as to achieve continuity between the various thicknesses of the traction lace 2 and the flexible means 1. The latter has a greater width than the traction lace 2. Thus a certain continuity between the dimensions of the traction lace 2 and of the flexible means 1 is obtained. The traction lace may for example be made of a Teflon-coated material.

Figure 4 diagrammatically depicts one exemplary embodiment of the device according to the invention.

15 The needle 3 comprises the proximal end 3b onto which the first end 2a of the traction lace 2 is attached. The latter has, for example, at each of its ends 2a and 2b, a loop 2c (cf. figures 5 and 6 respectively) obtained by ultrasonic welding, stitching or any other means.

20 One of these loops, 2c, is mounted on the proximal end 3b of the needle 3 while the other is mounted in the eye 4b.

25 During the procedure, it is thus possible to attach the end 2a of the traction lace 2 to the eye 4b either using the point 4c secured to said eye 4b or simply by running it through the closed loop that forms the eye 4b.

30 The device according to the invention therefore, for example, has a traction lace 2, the length of which is, for example, roughly equal to the length of the flexible means 1, namely a length of between 30 and 60 cm. Such dimensions or lengths of the traction lace 2 make it possible, if reference is made to the operative procedure, to avoid engaging the flexible means 1 in the body before being sure that the path taken by the needle 3 and the traction lace 2 is optimum. The long available length of traction lace 2 for carrying out the operative actions described thus

makes it possible for another path to be taken through the body if need be, without having to manipulate the flexible means 1.

By way of variation, it is possible to provide
5 the second end 1b of the flexible means 1 with an additional intermediate traction element, such as an additional lace like the one previously described under reference 2.

An additional traction lace 2 secured to the
10 free end 1b, which may also have an end piece 4 for this purpose, allows traction to be exerted in the opposite direction to its introduction on the flexible means 1, and allows it to back-track along its path if it is penetrating incorrectly.

15 According to another embodiment of the device according to the invention, depicted for example in figure 9, the intermediate traction element is a tubular element 20. The material of which the latter is made is, for example PVC.

20 The tubular element 20 is preferably semirigid, so that it can be screwed onto a threaded end 3c secured to the proximal end 3b of the needle 3. The other end of the tubular element 20 is connected, for example by screwing, to the flexible means 1 comprising
25 an end piece 30 secured to the sheath 5, for example by heat shrinking. The end piece 30 for this purpose has a complementary threaded part 30a (see figures 7 and 8).

The flexible means 1, the tubular element 20 and the two parts 3a, 3b of the puncturing needle 3 may
30 thus be assembled removably by screw fastening.

Other known removable means of connection or attachment may also be suitable in the context of the present invention.

The tubular element consists for example of a
35 number of parts of roughly the same length, for example 20 and 41, placed end to end and joined together removably by screw fastening. This end-to-end joining is obtained using a coupling 40 depicted in Figures 10, 11a, 11b and 11c.

The coupling 40 is made up of two elements, namely an internal connecting mandrel 42 and an external clamping bush 43.

At one end, the mandrel 42 has a threaded nipple 42b engaged in the tubular element part 41 and at the other end it has a stud 42a with teeth 42c intended to be engaged in the tubular element part 20 as depicted in figures 11b and 11c. The shape and dimensions of the teeth 42c tend to oppose separation of the tubular element part 20 from the mandrel 42.

Each mandrel 42 is associated with a bush 43 engaged on the tubular element part 41 so as to clamp part of said part 41 between the threaded nipple 42b and said bush 43.

The latter is also provided on the anterior end with a tapping 43a which bites by screwing into the material of which the abutting end of the part 20d' is made.

To begin with, one end of the part 41 of the tubular element is screwed onto the nipple 42b. The bush 43 is then attached to this end of the part 41, with the constituent material trapped between the screw thread of the nipple 42b and the sleeve 43, the latter also clamping the rest of the mandrel 42 except for the projecting stud 42a.

The two tubular element parts 20 and 41 are assembled by engaging the stud 42a in one end of said part 20 (figure 11b) and then by screwing the end of the bush 43 onto the exterior periphery of said part 20 (figure 11c). The turning of the bush 43 is depicted diagrammatically by the arrow R in figure 11c. The mechanical connection between the tubular element part 20 and the coupling 40 is thus improved.

The device according to the present invention makes it possible to implement a method for treating women suffering from urinary stress incontinence. This method will be specified herein below and allows the tape 6 to be fitted in the patient's body.

The treatment method comprises the steps consisting in:

a) forming an opening 103a in the anterior vaginal wall 103,

5 b) making two small suprapubic incisions 106, 107,

c) using the puncturing needle 3 connected to an intermediate traction means 2 or 20 to create a first path traveling around the pubic bone 105 and
10 emerging in the opening 103a formed in the anterior vaginal wall 103,

d) using the puncturing needle 3 connected to an intermediate traction means to create a second path around the pubic bone 105 and emerging in the opening
15 103a formed in the anterior vaginal wall 103,

e) using cystoscopy to check that the making of these paths has not punctured the bladder 101 or the urethra 100,

f) connecting the parts of the device emerging
20 from the opening 103a formed in the anterior vaginal wall 103,

g) pulling on the intermediate traction element 2 or 20 to adjust the loop formed by the flexible means 1 under the underside of the urethra 100,

25 h) separating and withdrawing the two halves of the sheath 5,

i) and leaving the tape 6 between the first suprapubic incision 106 and the second suprapubic incision 107 passing under the underside of the urethra
30 100.

According to one embodiment of the invention, the method consists in guiding the paths of the puncturing needle 3 along the posterior surface 105a of the pubis, by contact with the finger 50 of the surgeon
35 introduced through the opening 103a, formed in the anterior vaginal wall 103, as far as the lower edge 105b of the same side of the pubis 105.

According to one embodiment of the method according to the invention, the flexible means 1 is

attached to the intermediate element 2 or 20 after the check provided for in step (e) has been made.

According to one embodiment of the method according to the invention, the opening 103a made in the anterior vaginal wall 103 is vertical.

According to the method, a urethral probe 60 of the FOLEY balloon type is inserted into the patient beforehand.

According to one embodiment of the treatment method according to the invention, use is made of two intermediate traction elements 2 or 20 connected end to end during step (f).

According to another embodiment of the treatment method according to the invention, the puncturing needle 3 and the intermediate traction element 2 or 20 are separated once the check according to step (e) has been made and once the flexible means 1 has been introduced along the first path. This separation then makes it possible to create the second path using the puncturing needle 3 connected to the intermediate traction element 2 or 20.

All of the above defined steps are now described with a device according to figures 7 to 11 and the description relating thereto.

The first step (a) is illustrated in figure 12. The patient is placed in a gynecological position and a sterile operating zone is formed. A urethral balloon probe 60 is positioned in the bladder 101 and is connected to a sterile collecting bag to empty and flatten the bladder 101. A short vertical incision 103a, at most 30 mm long, is made in the middle of the vaginal wall 103, centered in the central third of the urethral canal 100 opening to the urinary meatus 100a. Each lip 103b of the vaginal incision 103a is detached from the underlying tissues using scissors 71 and appropriate instruments 70, as illustrated in figure 13.

Detachment is performed until the surgeon's index finger 50, introduced through the resulting

opening 103a, can reach the lower edge 105b of the pubis 105, away from the urethra 100 and the periurethral tissue (figure 14).

Next, a very small cutaneous incision 106, 107
5 less than 10 mm long is made in the abdominal skin immediately above the pubis 105, on each side of the centerline and about 20 mm away from the latter, to allow the percutaneous passage of the needle 3 just off the posterior face 105a of the pubis 30 in the
10 direction of the vagina 104.

The surgeon's index finger 50 is introduced into the vaginal passage thus prepared by detachment, and the active distal end 3a of the needle 3 follows a path to come into direct contact with this index finger
15 50. The path of the puncturing needle 3 is therefore perfectly controlled. The needle 3 can then reemerge through the vaginal opening 103a and the bladder 101 has remained completely safe from any injury by the needle.

20 In general, the straight percutaneous path is made first. The end of the intermediate traction element, for example the tubular element 20, reemerges behind the needle 3 via the vaginal opening 103a. This end of the traction element 20 is for example unscrewed
25 from the proximal end 3b of the needle 3 and is detached from the latter in the direction of the arrow S in figure 15.

The needle 3 is then passed along the second path (on the left-hand side in figure 16) in the same
30 way as for the first side (right-hand side). Once the distal part 3a of the needle is well away from the vaginal opening 103a, it can be detached by unscrewing its proximal portion 3b. This separation is depicted diagrammatically by the arrow T in figure 16.

35 The so-called proximal portion 3b is long enough to project when the percutaneous incision 107 is made.

By way of an alternative form according to the invention, the proximal portion 3b may be extended by

an additional tubular element 20 which projects out of the abdominal incision 107.

The next step consists in connecting the end of the tubular traction element 20 that follows the first path to the proximal portion 3b or to the additional tubular element 20 that follows the second path.

Connection is made using the coupling 40 depicted in figure 17.

The proximal portion 3b is then led back out through the abdomen by pulling in the direction of the arrow V illustrated in figure 18.

Before the flexible means 1 penetrates the patient's body, the tubular element 20 thus forms a loop around the urethra and its two ends reemerge respectively through the two abdominal cutaneous incisions 106 and 107 (figure 18).

The urethral probe 60 is then removed and cystoscopy is used to check for the absence of vesical perforation.

Once the check has been made, the end of the tubular element 20 that emerges from the abdominal incision 106 is assembled by screw fastening on the threaded end 30a of the flexible means 1 (sheath 5 plus tape 6) and the assembly is pulled (arrow V in figure 18) through the right and left paths to position the flexible means 1 under the urethra 100. When this positioning which corresponds to step (g) is complete, the ends 1a, 1b of the flexible means 1 reemerge from the abdominal incisions 106, 107 as depicted in figure 21.

The sheath 5 is then separated from the tape 6 by cutting said sheath 5 in its central zone 1c and withdrawing each of the halves 51 and 52 thus obtained through the corresponding abdominal incision 106, 107 according to step (h) (arrows W in figure 19).

The tape 6 is thus released, positioned and adjusted under the underside of the urethra 100, usually in a central position, without tension and without being squashed, as depicted in figure 20.

Once the sheath 5 has been withdrawn through each abdominal incision 106 and 107, the parts of the tape 6 which project out of said incisions 106 and 107 are cut off flush with the abdominal wall, said parts
5 being left at the subcutaneous site.

The cutaneous incisions are closed up using the conventional methods.

The tape 6 advantageously runs around the pubic bone 105 via its pelvic or deep face, and heads towards
10 the contralateral abdominal wall.

The resulting vaginal incision 103a made in the vaginal wall 103 is then closed once the definitive position of the tape 6 under the urethra 100 has been checked.

15 By way of a variation, the traction lace 2 can also be used for implementing said method.

The operating procedure thus used is notable in that it is a percutaneous operating technique because the dimension of the abdominal cutaneous incisions is
20 minimal, intended to be just enough to allow the needles to pass through and because the paths taken by the needle 3 are downwards, that is to say entering through abdominal incisions 106 and 107 to emerge through the predetermined and prepared corresponding
25 vaginal opening 103a.

This presents an enormous advantage from the safety point of view with respect to the risks of puncturing the bladder 101 on the one hand, and the iliac vessels on the other hand.

30 This is a considerable advantage over the known operating technique. The path can be checked by cystoscopy.

When it becomes apparent that the path is not appropriate, it is possible to withdraw the
35 intermediate traction element 2 or 20 to make a second path through the abdominal cutaneous incision 106, and to do so without introducing the flexible means 1 into the body.

All of the elements of the device according to the invention can thus be reused if the manipulation is incorrect, or if the path inside the patient's body needs to be improved or optimized. This represents a
5 considerable advantage over the state of the prior art.

Furthermore, the surgical technique described requires neither the use of an insertion tool for the needle, nor the use of an endovesical rod to move the bladder 101 and the urethra 100 away each time the
10 needle 3 passes on a downward path. This constitutes an advantageous simplification insofar as the surgical technique put forward in the state of the art entails the use of an endovesical rod twice, namely after each passage of each of the two needles which are making an
15 upward path.

It is to be noted that the device according to the invention is a percutaneous device, which is advantageous when compared with the known device which enters via the vaginal mucosa and emerges through the
20 skin in the abdominal suprapubic region.

It is notable that the extreme simplicity of the device according to the invention contributes not only to reducing its cost price and the number of its constituent parts but also to increasing the safety for
25 the patient and the quality of the result when the operating technique described in the present invention is implemented.

Checking the effect obtained on continence and adjusting the tension of the tape 6 are not justified
30 and this is for two reasons. Specifically, continence in a lying-down position is not comparable to the upright position, and the effectiveness of the tape is explained not by a gripping effect (which carries the risk of leading to stenosis) but by an effect of
35 providing uplifting support.

Furthermore, the operator chooses the position of the tape 6 with respect to the urethral duct 100 according to the clinical case being studied.

In the state of the art, this choice cannot be made, and continence tests are carried out after the bladder has been filled and coughing stress applied in order to adjust the tension in the tape, even though
5 the technique is supposedly said to be "tension free".

CLAIMS

1. A device for treating urinary stress incontinence in women, comprising:

- 5 - a flexible and elongate means comprising a tape for supporting the urethra and a protective sheath lying flat and enveloping said tape;
- a puncturing needle with an active distal end and a proximal end connected to a first end of the
10 flexible means,

wherein the proximal end of the puncturing needle is connected to the first end of the flexible means by virtue of an intermediate traction element, the second end of the flexible means being free or extended by an
15 additional intermediate traction element.

2. The device as claimed in claim 1, wherein the protective sheath completely envelopes the tape, including its first and second ends.

3. The device as claimed in claim 1 or 2, the
20 sheath of which can be split into two parts that can be separated by sliding them in two opposite directions relative to the tape, which device comprises a splittable means between the two central and adjacent ends of the sheath.

25 4. The device as claimed in claim 1 or 2, the sheath of which can be split into two parts that can be separated by sliding them in two opposite directions relative to the tape, which device comprises a filament arranged roughly at right angles to the longitudinal
30 axis of the sheath, so as to cut said sheath when traction is exerted on said filament.

5. The device as claimed in any of claims 1 to 4, wherein the sheath is made of a fluoropolymer-based heat-shrinkable material.

35 6. The device as claimed in any of claims 1 to 5, wherein the tape is formed from a macroporous knitted material.

7. The device as claimed in any of claims 1 to 6, wherein the tape in its central region has a resorbable

hydrophilic film reducing the risk of adhesion to or the risk of erosion of the urethra.

8. The device as claimed in any of claims 1 to 7, wherein the puncturing needle has a curved part continuously adjacent to a roughly straight part ending in its proximal end.

9. The device as claimed in any of claims 1 to 8, wherein the intermediate traction element is a traction lace.

10. The device as claimed in claim 9, and which comprises an end piece onto which the sheath is heat shrunk and to which the traction lace attaches.

11. The device as claimed in claim 9 or 10, wherein the traction lace has a length roughly equal to the length of the flexible means.

12. The device as claimed in any of claims 1 to 8, wherein the intermediate traction device is a tubular element.

13. The device as claimed in claim 12, wherein the tubular traction element and the puncturing needle are assembled by screwing.

14. The device as claimed in claim 12 or 13, wherein the tubular traction element consists of two parts of roughly the same length, placed end to end and joined together removably, for example by screwing using a coupling.

15. The device as claimed in any of claims 1 to 14, wherein the puncturing needle is the only puncturing needle.

16. The device as claimed in any of claims 1 to 15, wherein the tape is cut from an open knit made up of two layers formed by two threaded guide bars each - one full guide and one empty guide - these two bars being moved symmetrically for open mesh.

17. A device for treating urinary stress incontinence in women, substantially as hereinbefore described.
18. A device for treating urinary stress incontinence in women, substantially as hereinbefore described with reference to the drawings.



Application No: GB 0100554.5

Examiner: Susan Chalmers
(Mrs)

Claims searched: 1-18

Date of search: 13 June 2001

Patents Act 1977 Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.S): -

Int Cl (Ed.7): A61B: 17/04; A61F: 2/00

Other: ONLINE: EPODOC, WPI, JAPIO

Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
P,X	WO 00/74633 A (ETHICON) see Figures 5a-5c, page 8 line 23 to page 9 line 13, page 12 lines 4-18 and page 13 lines 28-29	1-4, 8, 9, 15 at least
Y	WO 98/35632 A (BOSTON SCIENTIFIC) see eg Figures 8A-8F	1,9
Y	US 6010447 (KARDJIAN) see eg Figures 3 and 5	1,9
Y	US 5899909 (CLAREN) see especially Figure 4 and column 3 lines 35-36	1-9,15

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☒ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☒ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.